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510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K020006**

Applicant information:

Date Prepared:	March 26, 2002
Name: Address	**Lens Dynamics, Inc.** 8600 W 14th Ave. Suite 2 Lakewood, CO 80215
Contact Person: Phone number:	Mr. Al Vaske (800) 228-2691

Reason for 510(k) submission: New Indication

Device Information:

Device Classification:	Class II
Classification Name:	Rigid gas permeable (hydrophobic) contact lens; Class II for daily Wear.
Classification #:	21 CFR 886.5916, Ophthalmic: 86 HQD
Trade Name:	Dyna Intra-Limbal Lens
Material Covered By:	enflufocon A; approved, 510(k) K943177 hexafocon A; approved, 510(k) K000795

Predicate Device:

The **Dyna Intra-Limbal Lens** (enflufocon A) or (hexafocon A) rigid gas permeable lens is substantially equivalent to the Boston ES (enflufocon A) and Boston XO (hexafocon A) RGP contact lens, which were cleared in 510(k) Premarket Notifications K943177 and K000795 respectively.

Device Description:

The **Dyna Intra-Limbal Lens** (enflufocon A) or (hexafocon A) rigid gas permeable spherical contact lens is intended for the correction of highly irregular corneas occurring naturally or from disease such as Pellucid Marginal Degeneration and keratoconus or from post surgery complications such as tilted grafts.

The design is larger in diameter, with a 11.2 mm standard diameter that is sized to fit within the limbus. A spherical peripheral system is employed to insure maximum exchange of tears and adequate cleansing of the cornea from flushing action behind the lens.

The lens material attributes and lens parameters are found in the package insert.

Intended Use:

The **Dyna Intra-Limbal Lens** (enflufocon or hexafocon A) rigid gas permeable contact lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons. The lens may be prescribed in otherwise non-diseased eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration or following penetrating keratoplasty. The lens may be disinfected using a chemical disinfection system.

Description of Safety and Substantial Equivalence:

The **Dyna Intra-Limbal Lens** (enflufocon A) or (hexafocon A) rigid gas permeable lens will be manufactured according to specified process controls and standards as identified in ANSI standard Z80.20-1998, and a cGMP quality assurance program currently in place.

The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the **Dyna Intra-Limbal Lens** manufactured in either (enflufocon A) or (hexafocon A) rigid gas permeable lens material is equivalent to the predicate devices identified previously. Authorization letters from Polymer Technology allowing the FDA to access all of their pre clinical and clinical data for these materials are enclosed. Reference 510(k) K943177 and K000795 respectively.

Shelf Life ~ The **Dyna Intra-Limbal Lens** is a hydrophobic rigid gas permeable contact lens material with <1% water content. Based on the Premarket Notification Guidance document for Daily Wear Lenses, shelf-life studies are not required for clearance of the **Dyna Intra-Limbal Lens.**

Solution Compatibility ~ The lens care regimes approved by Polymer Technology will be followed in the Dyna Intra-Limbal labeling.

The sponsor concludes data presented supports substantial equivalence of the **Dyna Intra-Limbal Lens** to the predicate devices and meets the requirements per section 510(k) of the act regarding substantial equivalence and *does not raise* different questions of safety and effectiveness than the predicate devices identified above. The difference between the predicates devices and the **Dyna Intra-Limbal Lens** is the addition of a new indication for use. Clinical data presented of 20 patients randomly selected for various corneal conditions supports efficacy of the **Dyna Intra-Limbal Lens.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2002

Lens Dynamics, Inc.
c/o Al Vaske, President
8600 West 14th Ave., Suite 2
Lakewood, CO 80215

Re: K020006
Trade/Device Name: Dyna Intra-Limbal Lens
Regulation Number: CFR 886.5916
Regulation Name: Daily Wear RGP Contact Lens
Regulatory Class: Class II
Product Code: HQD
Dated: December 24, 2001
Received: January 2, 2002

Dear Mr. Vaske:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

Device Name: **Dyna Intra-Limbal Lens**

INDICATIONS FOR USE:

The **Dyna Intra-Limbal Lens** (enflufocon or hexafocon A) rigid gas permeable contact lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons. The lens may be prescribed in otherwise non-diseased eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration or following penetrating keratoplasty. The lens may be disinfected using a chemical disinfection system.

(PLEASE DO OT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W. C. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K020006

Prescription Use X
(Per 21 CFR 801.109)

or

Over-The-Counter Use ___

(Optional Format 1-2-96)